

June 27, 1996, 5:04 p.m.  
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it could then sell the drug plus recover full damages for the period from the time that it could not sell the generic drug until the time the court determined that it could sell the drug. Additional provisions include a patent extension for the drug Lodine and modifications to patent extensions that are allowed under the Hatch/Waxman Act.

NOTE: Following the vote, the Pryor amendment, as amended, was adopted by voice vote.

**Those favoring** the amendment contended:

We know our colleagues sincerely believe in the merit of the Pryor amendment, plus we know that Senators are under tremendous pressure from special interest groups that have been demagoging this issue. However, for all the strident rhetoric we have heard, not one shred of evidence has been presented that pharmaceutical language was left out of the implementing legislation by mistake. Nevertheless, we are sympathetic to the argument that some generic drug manufacturers may have been harmed by the GATT patent extension for pharmaceuticals. Therefore, we have offered the Hatch amendment as an alternative to the Pryor amendment. The Hatch amendment, on a case-by-case basis, would leave it up to the courts to decide if a generic company had made a "substantial investment" to produce a drug before its patent was extended, and, if so, to entitle that company to produce the drug plus receive payment for the profits it could have received during the length of the court proceedings.

The TRIPS extended approximately 1 million patents. Of those 1 million patents, only 100 were for drugs. Many of those 1 million patents are held by companies based in Arkansas, but we have not heard the sponsor of the underlying amendment make any impassioned speeches about how we made a "mistake" in extending those patents without providing any grandfather clauses for generic companies. No, in only 1 case, pharmaceuticals, has he said that a mistake was made. Since this issue has become politicized, we know that the Administration has said that it was simply an oversight not to phase-in 20 year patents for drugs. However, we also know that the TRIPS was negotiated painstakingly over 3 Administrations during which time patent extensions and exemptions were considered for countless products. It is implausible if not impossible to believe that pharmaceuticals, which have a unique position under patent law, were overlooked by either the Administration or Congress. The Deputy Commission for Policy at the Food and Drug Administration (FDA) said last May that this "is not an example of Congress having overlooked a statutory provision it might have changed had it been aware of its existence" and the Court of Appeals for the Federal Circuit ruled last November that there is no legislative history showing that Congress ever had any intention of passing transition rules for pharmaceuticals. In fact, the Hatch/Waxman Act (which codifies the special rules that apply to pharmaceutical patents) was even amended by the implementing legislation, yet still no transition language was included.

Under the Hatch/Waxman Act, generic drug companies are given a unique right to infringe on drug company patents. They are allowed to use the research and development findings of "pioneer" drug companies when they apply for the right to make drugs in anticipation of their patents expiring. No other type of patents can be so infringed. Pharmaceutical information is extremely expensive to develop. Typically, it takes 12 years and \$350 million to \$500 million to gain approval for a new, pioneer drug. Under the Hatch/Waxman Act, generic companies get that information for free in order to help them get to market more quickly.

The TRIPS allows companies to try to prove in court that they had made substantial investments to begin making products in anticipation of the patents on those products expiring, and had then not been able to make those products because of TRIPS patent extensions. If a company could make that demonstration, it could infringe on a patent, provided that it made equitable remuneration to the patent holder. The Hatch amendment would give 2 extra rights to generic drug manufacturers that no other manufacturers would get for any of the other 100 million patents that were extended, while at the same time it would remain wholly consistent with the TRIPS requirements on court rulings and equitable remuneration. First, they would be entitled to damages for profits lost during adjudication. Second, they would get to try their cases under expedited procedures that would take no more than 7 months.

The underlying Pryor amendment, on the other hand, would violate the TRIPS by allowing production on the word of the generic drug companies alone, and solely on the basis of their filing an application using the pioneer company's data. After arduous negotiations, the United States managed to win that intellectual property rights agreement. Every year United States companies lose tens of billions of dollars due to theft of intellectual property rights. Many countries very reluctantly agreed to the TRIPS. If the United States were the first country to violate it, they would have all the excuse they needed to continue ignoring American patents. United States companies would thus lose tens of billions of dollars if the Pryor amendment were enacted.

We are not about to wreck a major international trade agreement as proposed by the Pryor amendment just to give generic pharmaceutical companies, solely on their word that their claims are meritorious, the right to sell patent-protected drugs. We think that if their claims have any merit they should stand up in court. The Hatch amendment is simple--it would tell the generic companies to prove their case, and, if they did, it would give them benefits that no other companies for any other products would get. The Hatch amendment provides a more than fair solution to something that we frankly do not believe is a problem. We urge Senators to support it as a fair alternative to the Pryor amendment.

**Those opposing** the amendment contended:

Though this issue is complex, all of the arguments boil down to a simple question of fairness. Should a drafting error in the GATT

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implementing legislation that unfairly burdens generic drug manufacturers and their customers be allowed to stand? The answer, clearly, is "no." When the United States passed its implementing legislation extending intellectual patents to 20 years, Congress forgot to add language saying that companies that were about to begin making drugs for which 17-year patents were about to expire could do so despite the new 20-year patent length that the GATT applied to pharmaceuticals. The GATT explicitly allowed such "grandfathering" legislation for pharmaceuticals and other patented products. The result of this mistake is that some drug companies are getting an extra 3 years of patent protection to which they are not entitled. In total, they will make an extra \$2.3 billion in profits, with a huge share of that amount going to one company, Glaxo. On the other side, generic companies that had purchased equipment, applied for the right to make the drugs, and otherwise prepared for marketing the drugs as soon as the patents expired have suffered large losses. Consumers, too, have been hurt, because they have had to continue paying higher prices for some name-brand drugs.

The Hatch amendment would fail to correct this problem. It would only allow a generic company to produce one of these drugs that has had its patent extended if it could prove in court that it had made a substantial investment in anticipation of a patent being lifted. While this proposal may sound fair, the burden of proof that the Hatch amendment would demand is so high that no company could reach it, and, even if a company could, during the intervening months consumers would still have to pay unfairly high prices. Making the Hatch amendment even worse, it also contains several special-interest items that would grant extensions for specific pharmaceutical patents.

The Pryor amendment, on the other hand, would provide a real correction. It would simply say that any generic company that had made a substantial investment to produce one of these drugs and that provided equitable remuneration to the company with the patent could begin production. Some of us believe that there might be trade repercussions from the Pryor amendment; others of us believe that the language of the amendment, which uses the definitions of "substantial investment" and "equitable remuneration" that are in the GATT agreement, avoids treaty conflicts. Either way, it is the right thing to do. The Patent Office, the Food and Drug Administration, and every other Federal expert has said that the United States simply forgot to put this grandfather clause in the implementing legislation. We urge our colleagues to reject the inadequate Hatch amendment in favor of the real solution offered by the underlying Pryor amendment.